Supreme Court, U.S.
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No. 01-660

In The

Supreme Court of the United States

ELI LILLY AND COMPANY.,

Petitioner,

v.

BARR LABORATORIES, INC.,
and
APOTEX, INC., and BERNARD C. SHERMAN,
and
GENEVA PHARMACEUTICALS, INC.,
and
INTERPHARM, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF RESPONDENT GENEVA PHARMACEUTICALS, INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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RESTATEMENT OF LILLY'S SECOND QUESTION PRESENTED

2. Did the District Court err by recognizing that Lilly could not resurrect a patent previously ruled invalid by filing a post-judgment terminal disclaimer, particularly where the terminal disclaimer, to be effective, must disclaim that portion of the patent term that extends beyond October 31, 2000, i.e., thus leaving no remaining patent term to resurrect?

PARTIES AND CORPORATE DISCLOSURE

There are no named parties other than those stated in the caption. Respondent Geneva Pharmaceuticals, Inc. is a wholly-owned subsidiary, through intervening wholly-owned subsidiaries, of Novartis AG.

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BRIEF IN OPPOSITION

In this brief in opposition to Eli Lilly Company's ("Lilly") petition for a writ of certiorari, respondent Geneva Pharmaceuticals, Inc. ("Geneva") will address only Lilly's second question presented for review, i.e., whether Lilly should be able to resurrect the '549 patent by filing a terminal disclaimer? As to the first question presented, whether the '549 patent is invalid for double patenting, respondent Barr Laboratories, Inc. ("Barr") has pointed out why Lilly's petition should be denied, and further comment by Geneva is unnecessary.

Even as to the second question, Barr correctly notes that Lilly's post-judgment offer to file a terminal disclaimer simply comes too late. Lilly's terminal disclaimer offer, and accompanying argument, is made for the first time in this Court, and for that reason alone renders the grant of Lilly's petition inappropriate.

That, however, may not entirely end the matter. Supreme Court Rule 15.2 admonishes counsel for respondent(s) "that they have an obligation to the Court to point out in the brief in opposition, and not later, any perceived misstatement [of fact or law] made in the petition."

Although the Barr opposition easily complies with Rule 15, particularly in noting (which Lilly's petition did not) that Lilly's terminal disclaimer offer and argument are presented for the first time in its petition, Geneva nevertheless believes that this Court is entitled to a detailed explanation of the underlying facts.

As will be explained below, not only is Lilly's second question presented untimely, but is so factually flawed as

to reflect adversely on the credibility of Lilly's entire petition.

Lilly's silence as to the timing of its fallback argument cannot shield it from further inquiry. At the very least, this Court is entitled to know *why* Lilly did not offer, before October 16, 2001 (when it filed its petition for a writ of certiorari), to disclaim any portion of the now-invalid '549 patent.

Lilly's Assertion that the "Federal Circuit Erred in Pre-Emptively Denying Lilly the Statutory Right to Terminally Disclaim the Molloy Patent" Is Disingenuous

Lilly ill-serves its cause when it asserts, as its fallback argument, that the Federal Circuit improperly denied Lilly the opportunity to "terminally disclaim" only that portion of the later-expiring '549 patent that extends beyond the expiration of the earlier-expiring Stark patent – i.e., the last seven months of the '549 patent. By this simple expedient, says Lilly, it should be able to recoup all but seven months of the 26 years of patent protection that Lilly had hoped to enjoy for its Prozac® product.

As noted in Barr's response, during the entire course of this lawsuit, including the briefing in the district court, the briefing on appeal leading up to the August 9, 2000, panel holding of invalidity for double patenting, the briefing on Lilly's petition for rehearing leading up to the May 15, 2001, revised panel holding, and the briefing on Lilly's second petition for rehearing, *never once* did Lilly come forward and offer to disclaim any portion of the '549 patent term "to preserve the validity of the Molloy

['549] patent." (Petition at 28). That Lilly fails even to acknowledge the lateness of its argument, much less explain it away, renders Lilly's argument unworthy of Supreme Court review.

Surely this could not have been an oversight. As correctly noted by Lilly, "[i]t is well-established that a common assignee is entitled to proceed with a terminal disclaimer to overcome a rejection based on double patenting of the obviousness type." (*Id.* at 27). If not an oversight, what actually did happen?

The answer is quite simple. In late 1997, Barr discovered that Lilly had issued to it *two* non-Molloy patents that claimed specific uses of fluoxetine. One was the Stark patent relied upon by the Federal Circuit in its second holding of invalidity. The other was U.S. Patent No. 4,329,356 to Holland. Stark, which had an expiration date of May 20, 2003, claimed the use of fluoxetine to treat anxiety. Holland, which had an even earlier expiration date of October 31, 2000, claimed the use of fluoxetine to treat hypertension.[1]

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[1] Claim 1 of Stark reads as follows:

1. A method for treating anxiety in a human subject in need of such treatment which comprises the administration of said human of an effective amount of fluoxetine or norfluoxetine or pharmaceutically acceptable salts thereof.

Claim 13 of Holland reads as follows:

13. A method for lowering blood pressure in hypertensive mammals in need of treatment which comprises the administration to such a mammal of an antihypertensive amount of fluoxetine or a pharmaceutically-acceptable salt thereof.

Immediately upon learning of these patents, both of which had expiration dates prior to the '549 patent, Barr notified Lilly that the '549 patent was invalid for double patenting based on either or both of Stark and Holland. In sharp contrast to its present last-ditch complaint that it should have been allowed to file a terminal disclaimer as to the last seven months of the '549 patent term, Lilly did not offer (even on a contingent basis) to disclaim any part of the '549 patent.

Instead it disclaimed the earlier-expiring Stark and Holland patents.

From that day forward, up to and through the Federal Circuit's May 15, 2001 panel decision, Barr consistently and strenuously argued that Lilly had disclaimed the wrong patents. Only by disclaiming the *later-issued* and *later-expiring* '549 patent could Lilly obviate the unlawful patent extension it had obtained by means of the '549 patent.

Not only did Lilly refuse to disclaim any part of the '549 patent, but its refusal was calculated and intentional, and indeed was borne of dire necessity.

The reason was that Lilly knew full well that if it were to terminally disclaim the '549 patent, this terminal disclaimer would have to date from the earliest expiration date of Stark *or* Holland. While Stark would expire on May 20, 2003 (a mere seven months prior to '549), Holland was to expire on October 31, 2000, i.e., over three years prior to the '549 patent's December, 2003 expiration. A terminal disclaimer of the '549 patent effective as of October 31, 2000, would have mooted this case as to

the '549 patent, since such a disclaimer would have provided Barr with all of the relief that it could have possibly obtained as to that patent – namely, its removal as a barrier to the launch of Barr's generic fluoxetine product on August 2, 2001 (when yet another of Lilly's fluoxetine patents expired). Lilly concedes as much in its petition, noting that if Holland had been relied upon by the Federal Circuit, a terminal disclaimer would have ended the inquiry, "because, unlike Stark, the Holland patent is now expired." (*Id.* at 28, n.10).

In a tacit admission that its double patenting problems did not reside solely with Stark, Lilly seeks, by way of the same footnote, to distinguish between Stark and Holland as a basis for a double patenting holding. According to Lilly, Holland "cannot support a double patenting holding . . . [because] it deals with peripheral effects of fluoxetine outside the brain and cannot, therefore, be linked to blockage of serotonin uptake in brain neurons as claimed in the Molloy patent." This Court will search the record in vain for any such argument in the courts below. Throughout this case, the double patenting issue as it related to Stark was briefed in conjunction and identically with Holland. They were addressed as a pair, with every argument and response applied equally to each.[2] Both patents claimed specific uses of fluox-

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[2] *See*, for example, Opening Brief of Appellant Barr Laboratories, Inc., heading at 38: "Lilly's Disclaimer Of The '356 [Holland] And '213 [Stark] Patents Cannot 'Undo' Its Double Patenting Violation." In Lilly's Brief, under the heading "Facts Relating to the Defense Based on the Holland and Stark Patents," Lilly argued that Holland and Stark present "virtually the identical situation" (Brief at 24). Lilly then proceeded to

etine; Stark to treat anxiety, Holland to treat hypertension.

Indeed, in the courts below, not only did Lilly fail to distinguish between Stark and Holland,[3] it offered the same basic argument with respect to both – namely, that by disclaiming Stark and Holland as soon as Barr cited them to Lilly as a basis for its double patenting defense, those patents became a nullity *nunc pro nunc*, and thus were entitled to the fiction that they never existed. Of course, and as noted above, Barr readily pointed out that Lilly had disclaimed the wrong patents, and that the only way to avoid the improper extension of the patent monopolies obtained and enjoyed by Lilly based upon Holland and Stark was to terminally disclaim that portion of the *'549 patent* that extended beyond the earliest expiration of Stark or Holland.

This is a matter of simple math and logic. Prior to the issuance of the '549 patent, Lilly had already enjoyed seven months of protection offered by Stark, and over *four years* of protection offered by Holland. Lilly went so far as to list these patents in the FDA "Orange Book," thereby effectively preventing third parties from obtaining FDA approval for the specific uses of fluoxetine claimed by Stark and Holland (i.e., to treat anxiety and hypertension, respectively). Since it was the *initial* terms

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offer five arguments, each with a caption that included "Holland and Stark" together. (*Id.* at 62-72).

[3] The Federal Circuit's reliance on Stark alone, rather than Holland or Holland/Stark was a matter of choice, judicial economy and restraint, it being unnecessary to set out a double basis for double patenting.

of Stark and Holland, when tacked on to the *full* later term of the patentably indistinct '549 patent, that resulted in the improper patent term extensions of Stark and/or Holland, the disclaimer by Lilly of the *terminal* portions of Stark and Holland was futile.

In fact, the Federal Circuit finding of which Lilly so bitterly complains (i.e., denying Lilly the right to terminally disclaim the '549 patent) was made in direct response to Lilly's then-argument that the disclaimer of Stark and Holland (but not the '549 patent) obviated the double patenting problem. The Federal Circuit expressly noted that the disclaimer by Lilly of Stark (and by extension Holland) aided Lilly not at all. As stated by the Federal Circuit, "[a] patent owner cannot avoid double patenting by disclaiming an earlier patent" (i.e., as Lilly tried to do by disclaiming Stark and Holland, both of which were "earlier" than the '549 patent). (Lilly petition, at 23a). The Federal Circuit's follow-on comment – i.e., that

> Further, because Lilly disclaimed the '213 patent, it cannot now terminally disclaim the '549 patent to expire at the time the '213 patent would have expired had it not been disclaimed. That is, the fact that the '213 patent has been disclaimed is of no help to Lilly, as double patenting precludes claim 7 of the '549 patent from extending beyond the termination date of the '213 patent, whether that termination date is at the end of its normal term, or as in this case, is the date it is terminated via disclaimer

– was not in response to any argument or offer made by Lilly. Rather, it was merely an observation that Lilly's ill-conceived disclaimer of Stark and Holland not only failed

to avoid double patenting, but that by its disclaimer of the wrong patents Lilly actually shot itself in the foot by putting in place an even *earlier* expiration date for Stark and Holland beyond which the '549 patent could not legally extend. Whether the terminal disclaimer of the '549 patent must be measured from 1977, when Lilly disclaimed Stark and Holland (as held to be the case by the Federal Circuit), or from October 31, 2000, when Holland would have expired if it had not been disclaimed, is of no moment. All that matters is that both deadlines have long since expired, and that Lilly's belated effort to disclaim only the last seven months of the '549 patent cannot right what the Federal Circuit properly held to be a fundamental wrong.

Moreover, Lilly's new-found and record-devoid argument that Holland "deals with peripheral effects of fluoxetine outside the brain" misses the point entirely. The Federal Circuit's holding that the claims of the '549 patent were not patentably distinct from the claims of the earlier-expiring Stark patent was based upon the unassailable fact (not here challenged by Lilly) that the '549 patent claims nothing more than the natural and inherent effect of fluoxetine when it is administered "for any purpose." As stated by the Federal Circuit,

> the limitation of claim 7 of the '549 patent directed to blocking serotonin uptake by use of fluoxetine hydrochloride is an inherent characteristic of the administration of fluoxetine hydrochloride *for any purpose, including* the treatment of anxiety.

(Lilly petition, at 29a; emphasis added).

Had Lilly chosen to urge below that the treatment of hypertension with fluoxetine hydrochloride (as claimed by Holland) may be attributable to some biological effect other than blocking serotonin uptake, *which it did not*,[4] the above-quoted finding would have been dispositive. Simply stated, it does not matter how fluoxetine works in the body to ameliorate the various maladies for which Lilly and others have obtained patents; all that matters is that the later-expiring '549 patent claims nothing more than the inherent biological effect of fluoxetine when it is administered "for any purpose." A later patent that does no more than claim such an inherent effect is not patentably distinct from an earlier patent directed to a specific use of fluoxetine. As further held by the Federal Circuit,

> That is, fluoxetine hydrochloride inherently blocks serotonin uptake upon administration. Therefore, no patentable distinction rests between administrating fluoxetine hydrochloride for treatment of anxiety and inhibition of serotonin uptake by administration of fluoxetine hydrochloride.

(*Id.* at 30a).

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[4] Lilly's conscious failure to argue in the courts below that Holland and Stark presented different double patenting issues is further explained by the fact that Holland, on its face, acknowledges that the "chief pharmaceutical activity of fluoxetine is as a specific inhibitor of the serotonin pump." So too does Stark: "[fluoxetine] has been found to block the uptake of . . . serotonin." As noted by the Federal Circuit, it is this serotonin uptake blocking effect that is "an inherent characteristic of the administration of fluoxetine hydrochloride for any purpose." (Lilly petition, at 29a).

To its credit, the Federal Circuit took special pains to explain this most basic of concepts. Citing the dissenting opinion of Judge Lourie in *Barroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223 (Fed. Cir. 1994), the Court pointed out that

> allowing a common owner to receive both a patent claiming the physical act of treating individuals . . . and a patent covering the result that such treatment accomplishes makes "no sense" . . . It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain relieving mechanism by means of that treatment is another.

(*Id.*).

Far from pre-emptively denying Lilly anything to which it was lawfully entitled, the Federal Circuit provided in advance the complete answer to the argument that Lilly now submits for the first time in this Court.

CONCLUSION

Even if Lilly were now permitted to terminally disclaim the '549 patent, such a disclaimer would have to be effective as of October 31, 2000. Such a disclaimer would have mooted Lilly's appeal in the Federal Circuit, and will moot Lilly's present petition. Lilly knew this when it decided in 1997 not to disclaim or even offer to disclaim the '549 patent; Lilly knows it now.

To the extent Lilly's untimely second question presented is entitled to any weight at all in this Court, it is solely in connection with Lilly's credibility and hence

entitlement to relief of any kind. By its apparent decision that it had nothing to lose by advancing its terminal disclaimer argument for the first time in this Court, Lilly comes very close to admitting that its entire petition is without merit.

Respectfully submitted,

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